IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

HEIDI MAHER,

Plaintiff,

-vs-

Case No. A-13-CA-543-SS

VAUGHN, SILVERBERG & ASSOCIATES, LLP d/b/a Texas Fertility Clinic; and AUSTIN IVF, LLP,

Defendants.

ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled cause, and specifically Plaintiff Heidi Maher's Motion for Partial Summary Judgment [#17], Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP (Defendants)'s Response [#19], Maher's Reply [#27], Defendants' Sur-Reply [#31], and Maher's Sur-Reply [#41]; Defendants' Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction [#21], Maher's Response [#29], Defendants' Reply [#35], Defendants' Supplement [#43], Defendants' Sur-Reply [#46], and Maher's Response to Defendants' Supplement [#44]; Defendants' Rule 12(b)(6) Motion to Dismiss Non-Cognizable Claims [#42], Maher's Response [#47], and Defendants' Reply [#49]; Defendants' Motion for Partial Summary Judgment [#51], Maher's Response [#59], Defendants' Reply [#66], and Defendants' Supplement [#67]; Maher's Motion for Summary Judgment on Application for Declaratory Relief [#53], Defendants' Response [#56], and Maher's Reply [#58]; and Defendants' Second Motion for Partial Summary Judgment [#71], Maher's Response [#75], and Defendants' Reply [#76]. Having considered the documents, the file as a whole, and the governing law, the Court

enters the following opinion and orders GRANTING Defendants' Rule 12(b)(1) motion and DISMISSING the case for lack of subject matter jurisdiction.

Background

Heidi Maher sought to become pregnant through an in vitro fertilization (IVF) procedure,[1] and she enlisted the services of Texas Fertility Center and Austin IVF to assist in the process. In preparation, Maher purchased sperm from two different donors, one vial from Donor 1999 and two vials from Donor 11076. *See* Mot. Dismiss [#21-2] Ex. B (Maher Dep.) at 74:17–20. While Donor 11076 was the backup option to Donor 1999, Maher considered both donors to be acceptable, at least for this first procedure. *Id.* at 81:23–82:8. With the help of Texas Fertility Center and Austin IVF, Maher became pregnant and gave birth to a child in 2009 using sperm from Donor 1999. *See* Am. Compl. [#70] ¶ 12. After the procedure, there were no more remaining vials of Donor 1999's sperm with Austin IVF, but Austin IVF retained custody of the sperm from Donor 11076. *See* Maher Dep. at 92:19–93:7.

In 2011, Maher turned to Texas Fertility Center and Austin IVF again as she desired a second child with the biological father of her first child, Donor 1999. Am. Compl. [#70] ¶ 12. Maher located a sperm bank with vials of Donor 1999's semen and arranged for that bank to send the vials to Austin IVF. *Id.* Austin IVF received the vials on June 21, 2011. *Id.* According to Maher, "[t]he

[1] IVF is a multi-step medical procedure in which a female patient's eggs are fertilized with sperm in a laboratory. Patients who choose to use an anonymous sperm donor are asked to select and purchase frozen semen, typically from a sperm bank. As the first step in the IVF procedure, the patient takes medications for approximately nine to fourteen days in order to produce eggs for retrieval. *See* Mot. Dismiss [#21-1] Ex. A (Hansard Dep.) at 39:15–40:11. Second, approximately thirty-six hours after the last medication is administered to the patient, the doctor performs a procedure to remove the eggs from the patient's ovaries. *Id.* at 40:12–17. Third, on the same day, a male donor's sperm cells are separated from the donor's semen, and the most normal sperm cells are then combined with the best-quality eggs in a lab to allow the sperm to fertilize the eggs. *Id.* at 40:17–20. Fourth, over the next several days, the fertilized eggs (embryos) are allowed to grow in the laboratory. *Id.* at 40:21–25. Fifth, the grown embryos are transferred into the patient's uterus. *Id.* Finally, the patient takes supplemental hormones for the ensuing nine to eleven days, and if an embryo implants in the lining of the patient's uterus and grows, a pregnancy can result. *Id.* at 41:1–6.

Lab Director for Austin IVF, Thomas G. Turner, took possession of the vials in his regulatory capacity as 'Responsible Person.'" *Id.*

On June 30, 2011, after retrieving Maher's eggs, employees of Austin IVF fertilized the eggs, but instead of fertilizing them with sperm from Donor 1999, they unintentionally used sperm from Donor 11076. *Id.* ¶ 13–14. According to Maher, "Donor 1999 was approved as eligible for use by the Austin IVF Lab Director, a Responsible Person as defined by federal law." *Id.* ¶ 14. Maher alleges Donor 11076 was not approved as eligible for use. *Id.* On July 7, 2011, employees of Austin IVF—unaware of their error—transferred three embryos to Maher. *Id.*

A week later, Maher was concerned her IVF procedure had failed and contacted Austin IVF. *Id.* ¶ 15. As she and Austin IVF representatives examined her case, they realized for the first time the wrong sperm had been used. *Id.* ¶ 15–16. Maher became upset both with Austin IVF's error and their treatment of her after they discovered their mistake. *Id.* ¶ 16–17. Eventually, however, her treating doctor, Dr. Lisa Hansard, told Maher new safety protocols would be implemented because of the incident. *Id.* ¶ 17. Also, in light of the mix-up and the fact Maher did not get pregnant during her second IVF procedure, Dr. Hansard persuaded Maher to try IVF again. *Id.* In August 2011, Maher underwent a third IVF procedure, this time properly using Donor 1999. *Id.* ¶ 18. The third effort did not successfully result in a pregnancy. *Id.* ¶ 19.

Still upset about the second procedure, Maher complained to Austin IVF, and a meeting took place on November 6, 2011. *Id.* ¶ 20. According to Maher, Austin IVF representatives claimed Maher selected Donor 11076 for the June 30, 2011 procedure, and they produced her chart, which indicated her selection of Donor 11076. *Id.* Maher claims Austin IVF falsely inserted those chart notes to make it look like she selected Donor 11076 once they realized their mistake, as they knew

she wanted Donor 1999. *Id.* ¶ 21.

Based on this series of events, Maher filed this lawsuit in federal court against non-diverse Defendants Vaughn, Silverberg & Associates, LLP d/b/a Texas Fertility Center, incorrectly named in the complaint as "Texas Fertility Clinic," and Austin IVF, LLP. She asserts the following causes of action: (1) "Federal Violations and Negligence Per Se" (*Id.* ¶¶ 24–40); (2) "Negligent Hiring, Supervision, and/or Management" (*Id.* ¶¶ 41–42); (3) "Promissory Estoppel" (*Id.* ¶¶ 43–44); "Offensive Physical Contact or Battery" (*Id.* ¶¶ 45–46); and (5) "Intentional Infliction of Emotional Distress" (*Id.* ¶ 47). Maher seeks damages for past and future medical expenses; past physical pain and suffering; past loss of time and earnings; past and future mental anguish; pecuniary and consequential damages; and exemplary damages. *Id.* ¶ 48–49. Finally, Maher seeks declaratory and injunctive relief in connection with documents Defendants allegedly placed in Maher's medical records and which Maher wants removed. *Id.* ¶ 50.

Since the initiation of the lawsuit, the parties have conducted discovery and currently have pending before the Court a number of motions to dismiss and motions for partial summary judgment. The only motion requiring any analysis by the Court, however, is Defendants' threshold motion to dismiss for lack of subject matter jurisdiction.

Analysis

Defendants move to dismiss Maher's case pursuant to Rule 12(b)(1) as they contend her amended complaint does not invoke this Court's federal question jurisdiction under 28 U.S.C. § 1331.[2]

[2] Maher filed her original complaint on June 28, 2013. *See* Compl. [#1]. On March 31, 2014, Defendants filed their Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction [#21] based on the original complaint. On April 23, 2014, Maher filed her Amended Complaint [#36]. On June 7, 2014, Maher filed a Motion for Leave to File

I. Allegations and Facts Concerning Subject Matter Jurisdiction

At the status conference held October 21, 2014, Maher's counsel conceded the plaintiff's theory of the case is novel concerning its basis for federal jurisdiction. After review of the amended complaint, the Court does not find its jurisdictional allegations to be a model of clarity but rather a hodgepodge of references to federal regulations and statutes. This scattershot approach appears to be made in the hope one of the references might stick or perhaps that the Court, taking all of these references in the aggregate, will manufacture federal jurisdiction under circumstances the plaintiff admits no other court has ever found jurisdiction. The result is a confusing and meandering pleading. Nevertheless, the Court attempts to describe the alleged bases for federal jurisdiction.

Generally, Maher's argument is that "[t]o assume uniformity, proficiency, and sensitivity, Congress empowered federal oversight of assisted human reproduction," and "[t]he field is occupied by federal law." *Id.* ¶ 1. Moreover, Maher contends "[g]aps in federal statutory provisions may be filled by interstitial federal common law." *Id.* ¶ 6. As support for the notion Congress "has enacted a general regulatory scheme for assisted reproduction," Maher first cites the Code of Federal Regulations on Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). *Id.* (citing 21 C.F.R. § 1271). Section 1271 is a federal regulation promulgated by the United States Food and Drug Administration (FDA), the purpose of which "is to create a unified registration and listing

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Amended Complaint [#50], which sought leave to file the same amended complaint filed April 23, 2014. While Defendants opposed the motion for leave for a variety of reasons, the deadline for filing amended pleadings in the scheduling order was June 28, 2014. *See* Order of Oct. 8, 2013 [#8]. The Court granted the motion for leave on October 22, 2014, and Maher's First Amended Complaint (the same as the amended complaint filed April 23, 2014) was docketed as entry #70. While Defendants filed their Rule 12(b)(1) motion prior to the filing of the amended complaint, the Court still applies the motion to the amended complaint for two main reasons. First, Defendants filed a Supplement [#43] and a Sur-Reply [#46], which addressed Maher's allegations in her amended complaint. Second, Defendants indicated at the status conference held October 21, 2014, that they wanted to stand on their Rule 12(b)(1) motion and have the Court apply it to the amended complaint.

system for establishments that manufacture [HCT/Ps] and to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by [HCT/Ps]." 21 C.F.R. § 1271.1(a). Second, Maher cites the Clinical Laboratory Improvement Act (CLIA), which sets the standards and certificate requirements for clinical laboratory testing. Am. Compl. [#70] ¶ 1 (citing 42 U.S.C. § 263a).

In addition, Maher contends Defendants "[t]out [f]ederal [l]aw and [c]ertification" through their website and marketing materials by which they represent to the public they must earn a certificate through CLIA and are subject to unannounced inspection by the FDA. *Id.* ¶ 7. According to Maher, "Defendants should be estopped from inviting public trust by virtue of federal law, while at the same time denying the Court's authority to decide if they have complied with federal law." *Id.*

Maher also highlights Defendants' membership in the American Society for Reproductive Medicine (ASRM). *Id.* ¶ 8. Maher alleges the ASRM held a meeting and published an executive summary describing federal regulation of assisted reproductive technology (ART), including: (1) the Centers for Disease Control and Prevention (CDC)'s "collect[ion] and publish[ing] of data on ART procedures;" (2) the FDA's "control[] [of] approval and use of drugs, biological products, and medical devices and [its] jurisdiction over screening and testing of reproductive tissues, such as donor eggs and sperm;" and (3) the Centers for Medicare and Medicaid Services (CMS)'s responsib[ility] for implementation of the [CLIA] to ensure the quality of laboratory testing." *Id.* Maher alleges that by describing these federal regulations, the ASRM "[c]oncede[s] the [w]eight of [f]ederal [l]aw," and "proclaim[s] the significance of federal law." *Id.* Because Defendants are

members of this "supervisory institution," Maher concludes "this case is permeated with substantial federal issues." *Id.* ¶ 9.

More specifically, Maher asserts a number of different federal issues she believes are embedded in her claims. Maher first argues Defendants violated various provisions of 21 C.F.R. § 1271, Subpart C including: (1) § 1.271.45(c) stating "[a]n HCT/P must not be implanted, transplanted, infused, or transferred until the donor has been determined to be eligible"; (2) § 1.271.47(d) providing "[y]ou must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence"; and (3) § 1.271.50(a) stating "[a] responsible person, as defined in § 1.271.3(t), must determine and document the eligibility of a cell or tissue donor." *Id.*

Based on these provisions, Maher posits a number of questions she contends require resolution by a federal court, including: (1) "Pursuant to federal law, does a federally registered HCT/P Establishment owe a legal duty to not use sperm that is not approved as eligible for use by a Responsible Person?"; (2) "Pursuant to federal law, does a federally registered HCT/P Establishment owe a legal duty to verify that sperm meets criteria for release prior to use with in vitro fertilization?"; and (3) "If a federally registered HCT/P Establishment . . . in concert with its partner . . . approves an IVF candidate's selection of donor sperm as eligible for use, but instead uses donor sperm that is not approved by a Responsible Person—and which is not selected for use by the IVF recipient on the occasion in question—does federal law require one or both of the HCT/P Establishments to report the incident to the FDA under 21 C.F.R. [§ 1.271] Subpart C?" *Id.*

Maher suggests a few other related questions she claims demand a federal court's attention such as: (1) "Is a Responsible Person exempt from the strictures of current good tissue practice

(CGTP) set forth in 21 C.F.R. Subpart D?"; (2) "Does the federal regulatory scheme applicable to assisted reproduction obligate Austin IVF or Texas Fertility Center to report substantial complaints or deviations—such as use of the wrong sperm—to the FDA, the CDC, or CMS?"; (3) "Does the federal regulatory scheme applicable to assisted reproduction supply a remedy to consumers when a Clinical Laboratory (42 U.S.C. § 263a), an Embryo Laboratory (42 U.S.C. § 263a-7), an HCT/P Establishment (21 C.F.R. § 1271.3(b)), or a Responsible Person (21 C.F.R. 1271.3(t)), engages in misinformation, cover-up or retaliation against a complainant?"; and (4) "If there are gaps in the federal scheme applicable to assisted reproduction, does interstitial federal common law afford a remedy to effectuate the statutory scheme?" *Id.*

In addition to subparts C and D of 21 C.F.R. § 1271, Maher also invokes subpart E in claiming "a Responsible Person should 'maintain complaints . . . [and the] complaint file must contain sufficient information about each complaint for proper review and evaluation . . . and for determining whether the complaint is an isolated event or represents a trend.' 21 C.F.R. [§] 1271.320(b)." *Id.* ¶ 29. Maher continues: "A Responsible Person should report HCT/P deviations to the FDA, and '[e]ach report must contain a description of the HCT/P deviation, information relevant to the event and manufacture of the HCT/P involved . . . .' 21 C.F.R. [§] 1271.350(b)." *Id.*

As her final basis for federal jurisdiction, Maher contends "Defendants should be subject to civil penalties and other orders—remedies analogous to federal remedies available under the Federal False Claims Act. 31 U.S.C. § 3729(a)(1)(A–C and G)." *Id.* ¶ 33. Maher explains this federal-theory-of-jurisdiction-by-analogy as follows: "The False Claims Act imposes liability on those who employ false means to gain or keep a benefit from the federal government (e.g., FDA approval as

a Registered HCT/P Establishment), or to avoid an obligation to transmit property to the federal government (e.g., reports and complaints and deviations, Form FDA 3486)." *Id.* ¶ 36. Apparently, Maher contends that Defendants' alleged failure to report their mistake to the FDA and their alleged fraudulent after-the-fact alteration of Maher's medical records is akin to a violation of the False Claims Act, and therefore remedies available under that statute should be available to Maher. *Id.* ¶¶ 36–37.

II. Legal Standards

A. Subject matter jurisdiction and Rule 12(b)(1)

"A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss., Inc. v. City of Madison, Miss.*, 143 F.3d 1006, 1010 (5th Cir. 1998). Federal courts are of limited jurisdiction. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001) (citing *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). Courts "must presume that a suit lies outside this limited jurisdiction, and the burden of establishing federal jurisdiction rests on the party seeking the federal forum." *Id.* Therefore, while Defendants are the movants, Maher nevertheless bears the burden to establish subject matter jurisdiction.

Federal Rule of Civil Procedure 12(b)(1) governs challenges to a court's subject matter jurisdiction. *See* FED. R. CIV. P. 12(b)(1). The Fifth Circuit Court of Appeals authorizes two types of challenges under Rule 12(b)(1): a "facial attack" and a "factual attack." *See Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981). When a defendant files a 12(b)(1) motion unaccompanied by supporting evidence, it is considered a facial attack, and "the trial court is required merely to look to the sufficiency of the allegations in the complaint because they are

presumed to be true." *Id.* On the other hand, a factual attack challenges the Court's subject matter jurisdiction irrespective of the pleadings, and therefore, in reviewing a factual attack, matters outside the pleadings are considered, such as "affidavits, testimony, or other evidentiary materials." *Id.*

In the event of a factual attack, "a plaintiff is also required to submit facts through some evidentiary method and has the burden of proving by a preponderance of the evidence that the trial court does have subject matter jurisdiction." *Id.* Unlike a facial attack, when a defendant makes a factual attack, "no presumptive truthfulness attaches to a plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Williamson* v. *Tucker*, 645 F.2d 404, 413 (5th Cir. 1981). Rather, "the trial court is free to weigh the evidence and resolve factual disputes dispositive of subject matter jurisdiction[.]" *Montez v. Dep't of Navy*, 392 F.3d 147, 149 (5th Cir. 2004). In conducting that inquiry, the Court may consider: "(1) the complaint alone; (2) the complaint supplemented by undisputed facts; or (3) the complaint supplemented by undisputed facts plus the Court's resolution of disputed facts." *Id.* Ultimately, dismissal is warranted if the plaintiff's allegations, together with any undisputed facts, do not establish the Court has subject matter jurisdiction. *See Hobbs v. Hawkins*, 968 F.2d 471, 475 (5th Cir. 1992).

B. The well-pleaded complaint rule and the standard for federal jurisdiction

Pursuant to Article III and 28 U.S.C. § 1331, federal courts only have "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. "[T]he question of whether a claim 'arises under' federal law must be determined by reference to the 'well-pleaded complaint.'" *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (citation omitted). A plaintiff could establish federal question jurisdiction by alleging

a state cause of action that Congress has transformed into an inherently federal claim by completely preempting the field. *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63–64 (1987). More typically, "[a] federal question exists only [in] those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Singh v. Duane Morris LLP*, 538 F.3d 334, 337–38 (5th Cir. 2008) (internal quotation omitted).

Regarding this latter category of "necessary resolution" cases, the "mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." *Merrell Dow*, 478 U.S. at 813. Likewise, "the presence of a disputed federal issue . . . [is] never necessarily dispositive." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). Instead, the "necessary resolution" language, "far from creating some kind of automatic test, . . . recognize[s] the need for careful judgments about the exercise of federal judicial power in an area of uncertain jurisdiction." *Merrell Dow*, 478 U.S. at 814.

The Supreme Court has summed up the relevant inquiry concerning whether federal jurisdiction exists: "[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314. The Fifth Circuit has broken down this inquiry into four factors: "(1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh*, 538 F.3d at 338.

II. Application

To establish federal jurisdiction, Maher's complaint must establish: (1) federal preemption, (2) federal law creates the cause of action, or (3) her right to relief necessarily depends on resolution of a substantial question of federal law.

A. Field Preemption

As an initial matter, it is not entirely clear whether Maher is even making a preemption argument. The confusion stems from Maher's summary statement in her Amended Complaint that "Congress has enacted a general regulatory scheme for assisted reproduction—the field is occupied by federal law." Am. Compl. [#70] ¶ 6. While this sentence seemingly references the notion of "field preemption," Maher does not explain this contention beyond the one sentence, be it in her complaint or any other pleading. Defendants do not mention the issue either. Nonetheless, to be clear, the Court briefly addresses the preemption issue.

In determining whether federal law preempts state law, Congressional intent is the paramount consideration. *Cal. Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987). Preemption may manifest in several different ways, including impliedly where Congress's preemptive intent may be inferred if the federal scheme is so comprehensive it "occup[ies] the field," leaving no room for supplementary state law. *Id.* at 280–81. Maher primarily references: (1) 21 C.F.R. § 1271, which is promulgated by the FDA for the purpose of "creat[ing] a unified registration and listing system for" HCT/P establishments and "to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases" by HCT/Ps; and (2) the CLIA, which sets the standards and certificate requirements for clinical laboratory testing. Am. Compl. [#70] ¶ 1. Maher, however, cites no legislative history (or case law)

suggesting Congress intended to create a federal scheme in the area of HCT/Ps or laboratory testing so comprehensive that there is no room for state law negligence and medical malpractice claims. In short, to the extent Maher suggests field preemption applies to the circumstances of this case, the Court rejects the argument.

B. Federal Question

Moving onto the question of whether a federal question exists, Maher does not contend any federal law actually creates the cause of action she asserts. Therefore she must show jurisdiction exists under the "necessary resolution" theory, and the Court applies the factors as described in *Singh* to determine whether Maher satisfies her burden. "If any one of these four prongs is not satisfied, a court should not exercise federal-question jurisdiction." *Marren v. Stout*, 930 F. Supp. 2d 675, 681 (W.D. Tex. 2013).

1. Is resolving a federal issue necessary?

While Maher raises a host of "federal issues," the only one Maher asserts that carries any weight at all is her contention Defendants violated various FDA regulations, and in so doing, were negligent.[3] Resolution of whether Defendants violated the FDA regulations, however, is not necessary to determining whether Defendants acted negligently. "When a claim can be supported by alternative and independent theories of recovery, one based on state law and the other on federal law, that claim may not form the basis for federal question jurisdiction because federal law is not a 'necessary' element of the claim." *Goffney v. Bank of Am., N.A.*, No. H-12-1868, 2012 WL

[3] For example, Maher's "federal issues" concerning (1) Defendants' advertisements publicizing their compliance with federal regulations, and (2) Defendants' membership in an organization which described various federal regulations in an executive summary of a meeting do not seriously create a basis for federal jurisdiction. In support of these issues, Maher only offers attorney argument and fails to provide any case law.

4127952, at *4 (S.D. Tex. Sept. 17, 2012) (citing *Willy v. Coastal Corp.*, 855 F.2d 1160, 1170–71 (5th Cir. 1988) (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 810–13 (1988)).

Here, Maher asserts two theories of liability in support of her negligence cause of action: (1) negligence *per se*; and (2) negligent hiring, supervision, and management.[4] She premises the former on violations of the FDA regulations, but bases the latter on Defendants' allegedly: (1) failing "to provide competent personnel to validate and verify the sperm intended for in vitro fertilization;" and (2) instructing or allowing "personnel to misrepresent Maher's medical history and lab information." Am. Compl. [#70] ¶ 41. The issue of whether Defendants violated the FDA regulations is therefore not "a necessary element" of Maher's negligence cause of action because she asserts an "alternative and independent" theory to support it. As such, Maher fails to satisfy the first factor.

2. Is the federal issue actually disputed?

Defendants concede that, to the extent the "federal issue" is whether they violated the FDA regulations, they dispute that issue. *See* Mot. Dismiss [#21] at 14–15. Therefore, Maher satisfies the second factor.

3. Is the federal issue substantial?

"[F]ederal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal

[4] "Negligence *per se* is a theory or 'doctrine' that assists a party in proving negligence rather than an independent state tort action." *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 771 (5th Cir. 2011); *see also Gray ex rel. Rudd v. Beverly Enters.-Miss., Inc.*, 390 F.3d 400, 407 (5th Cir. 2004) (explaining "[n]egligence *per se* . . . is a theory, by which statutes are used to establish the appropriate standard of care."); *Martin v. Avis Rent-A-Car Sys., Inc.*, 932 S.W.2d 697, 699 (Tex. App.—Houston [14th Dist.] 1996, writ denied) (noting "Appellants . . . assert only negligence theories, including ordinary negligence, negligence *per se*, gross negligence, negligent hiring, and negligent supervision. An essential element to any theory of negligence is proximate cause."). Therefore, while Maher asserts negligence *per se* based on the alleged FDA violations as "Count One" and negligent hiring, supervision, and management as "Count Two," these two counts are actually two different theories for proving a negligence cause of action. *See* Am. Compl. [#70] at 11, 16.

forum." *Singh*, 538 F.3d at 338. In *Merrell Dow*, the plaintiffs had sued a drug manufacturer based on alleged birth defects incurred by children born to mothers who had taken the drug Bendectin during pregnancy. *Merrell Dow*, 478 U.S. at 805. Five of the six counts were based on common law theories of negligence, breach of warranty, strict liability, fraud, and gross negligence. *Id.* One of the counts involved the allegations that Bendectin was "misbranded" in violation of the Food, Drug, and Cosmetic Act (FDCA) and the violation of the FDCA "constitute[d] a rebuttable presumption of negligence." *Id.* The Supreme Court held these allegations were insufficient to create federal jurisdiction. *Id.* at 814. The Fifth Circuit summarized the *Merrell* decision as holding "where Congress has provided no private remedy for the violation of a federal drug regulatory statute, the fact that violation of the statute is an element of a state tort claim is insufficient to establish a substantial federal interest." *Singh*, 538 F.3d at 338–39 & n.4.

Other factors to consider on the substantiality question include whether: (1) the case presents a nearly pure issue of law that would control many other cases rather than an issue that is fact-bound and situation-specific; (2) the federal government has an important interest in the issue, particularly if the case implicates a federal agency's ability to vindicate its rights in a federal forum; and (3) a determination of the federal question will be dispositive of the case. *Marren*, 930 F. Supp. 2d at 683 (distilling these sub-factors from recent Supreme Court precedent).

As an initial matter, the circumstances of this case strongly resemble those in *Merrell Dow*, and the Supreme Court's analysis and holding make clear Maher has failed to establish a substantial federal interest. Like the plaintiffs in *Merrell Dow* who alleged violation of the FDCA via misbranding of Bendectin as an element of their negligence claim, Maher alleges violations of 21 C.F.R. § 1271 as an element of her negligence cause of action. These pleading strategies represent

efforts to effectively create a federal cause of action for violations of federal statutes or regulations where Congress declined to do so. The *Merrell Dow* Court specifically rejected this approach as a basis for federal jurisdiction. *See Merrell Dow*, 478 U.S. at 812.

Furthermore, the sub-factors described in *Marren* all indicate Maher's "federal issue" is not substantial. First, whether Defendants violated the FDA regulations when they mistakenly used the wrong sperm in Maher's second IVF procedure and subsequently failed to report the incident is a fact-bound, situation-specific set of determinations. *See Cardenas v. Apartment Inv. & Mgmt. Co.*, No. SA-12-CV-962-XR, 2012 WL 6004212, at *7 (W.D. Tex. Nov. 29, 2012) (concluding whether the defendant violated the federal statutes and regulations governing federally-subsidized housing involved "fact-based inquiries that do not present a substantial federal question or implicate important federal interests"); *Windle v. Synthes USA Prods., LLC*, No. 3:11-CV-2591-D, 2012 WL 1252550, at *7 (N.D. Tex. Apr. 13, 2012) (explaining "[i]f the claim merely requires determining whether defendants did or did not make an FDA-required disclosure, the issue whether the failure to make the disclosure renders defendants liable under a pleaded theory of state law, which does not necessarily require the resolution of a substantial federal issue."); *RX.com, Inc. v. O'Quinn*, 766 F. Supp. 2d 790, 796 (S.D. Tex. 2011) ("In contrast to *Grable*, the state court in this case will be asked to decide nothing more far-reaching than whether defendants are liable to plaintiffs. Therefore, as was the case in *Singh*, federal law is only 'tangentially relevant' to this inquiry, amounting to no more than an inquiry necessary to establish an element of a state law claim. The federal interest in this case is not substantial.").

Second, the federal government does not have an important interest in the outcome of this lawsuit. Maher has not challenged the actions of the FDA, which is the agency responsible for

enforcement of the regulations at issue, nor do the Defendants. As such, the FDA "is not a party to this case and accordingly would not be bound by a court's determination of" any issues presented at trial or in a pre-trial proceeding. *Marren*, 930 F. Supp. 2d at 687.

Third, resolution of Maher's "federal issue" will be not be dispositive of this case. Even if Maher ultimately established Defendants violated the relevant FDA regulations, she would still need to establish additional elements of her claim in order to dispose of the case. Negligence *per se* "provides only a way of proving duty and breach of duty, and causation and damages must still be established." *All Freight Sys. v. James*, 115 F. App'x 182, 184 (5th Cir. 2004) (unpublished) (citing *Parrot v. Garcia*, 436 S.W.2d 897, 899–900 (Tex. 1969)).

In sum, Maher fails to establish a substantial federal issue, the third factor under the *Singh* test.

4. Will federal jurisdiction disturb the balance of federal and state judicial responsibilities?

Finally, the fourth factor described in *Singh* strongly militates toward dismissal for lack of subject matter jurisdiction. "In determining whether 'arising under' jurisdiction exists, courts must be careful not to open the federal courthouse doors to traditionally state cases." *Cardenas*, 2012 WL 6004212 at *7. In *Merrell Dow*, the Supreme Court was hesitant to find federal jurisdiction for negligence *per se* cases based on violations of the federal FDCA due to the potential increase in federal litigation. *Merrell Dow*, 478 U.S. at 811–12.

While Maher has gone through great effort to avoid labeling her claims as medical malpractice claims, her creative pleading cannot alter the reality that her allegations amount to state law claims under Chapter 74 of the Texas Civil Practices and Remedies Code. Chapter 74

establishes substantive and procedural provisions to be applied in a lawsuit asserting a "health care liability claim." "Chapter 74 does not a create a separate cause of action, but rather governs all tort claims that are considered 'health care liability claims' as defined by the statute." *Rodriguez v. Christus Spohn Health Sys. Corp.*, 628 F.3d 731, 736 (5th Cir. 2010).

A "health care liability claim" is defined as:

> . . . a cause of action against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately results in injury to or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.

TEX. CIV. PRAC. & REM. CODE § 74.001(13).

To determine whether a claim is a "health care liability claim," the court must examine the underlying nature of the claim. *Garland Cnty. Hosp. v. Rose*, 156 S.W.3d 541, 543 (Tex. 2004) (addressing Chapter 74's predecessor statute, the Medical Liability and Insurance Improvement Act, which used the same definition for "health care liability claim"). A plaintiff "cannot use artful pleading to avoid [the statute's] requirement when the essence of the suit is a health care liability claim." *Id.* "If the act or omission alleged in the complaint is an inseparable part of the rendition of health care services, then the claim is a health care liability claim." *Id.* at 544 (citation omitted).

A review of Maher's complaint demonstrates her allegations revolve around alleged breaches of duties Defendants supposedly owed Maher as health care providers. Simply put, Maher sought Defendants' services for a medical procedure in order to become pregnant, and Defendants allegedly failed in their roles as health care providers when they used the wrong sperm. The Court concludes these allegations easily fall within the purview of "health care liability claims" as defined by Texas law. Texas courts confronting the issue agree. *See Saleh v. Hollinger*, 335 S.W.3d 368, 373–76

(Tex. App.—Dallas Jan. 4, 2011, pet. denied) (holding the plaintiff's claims against a fertility clinic regarding alleged intentional misrepresentations and theft and sale of her eggs constituted health care liability claims); *Inst. for Women's Health, P.L.L.C. v. Imad*, No. 04-05-00555, 2006 WL 334013, at *1–3 (Tex. App.—San Antonio Mar. 16, 2006, pet. denied) (mem. op.) (holding the plaintiff's claims against a fertility clinic alleging an embryologist improperly handled, stored, and/or transported the plaintiff's embryos constituted health care liability claims).

Medical negligence claims have traditionally been within the domain of Texas law, and federal law should not interfere with the power of state authorities to regulate the practice of medicine. *See Singh*, 538 F.3d at 339 ("[F]ederal jurisdiction over this state-law [legal] malpractice claim would upend the balance between federal and state judicial responsibilities."). "Because federal 'jurisdiction to hear a state-law claim always raises the possibility of upsetting the state-federal line drawn (or at least assumed) by Congress, . . . there must always be an assessment of any disruptive portent in exercising federal jurisdiction.'" *Id.* (quoting *Grable*, 545 U.S. at 314). Exercise of federal jurisdiction over Maher's claims would disturb the balance of federal and state judicial responsibilities.

Having examined the *Singh* factors, the Court finds Maher only satisfies one of the four, and as a result, she fails to establish the existence of a federal question over which the Court should exercise jurisdiction.

C. False Claims Act

As a final "Hail Mary" attempt at federal jurisdiction, Maher asks the Court to create a remedy for her "analogous to remedies available under the Federal False Claims Act." Am. Compl. [#70] ¶ 33. Leaving aside the inaptness of the analogy, the Court merely notes Maher cites no

authority to support her request, and the Court rejects it.

Conclusion

In the Court's view, Maher's invocation of various federal hooks in her complaint is an effort to avoid Texas medical malpractice law. In so doing, Maher asks this federal district court of limited jurisdiction to fashion a federal cause of action and remedy when both Congress and the FDA have declined to do so and when no other federal court has accepted a similar invitation. This Court follows the law; it does not make the law. Lacking subject matter jurisdiction, the Court must dismiss the case without prejudice. Because Maher has already filed an amended complaint—and did so after the Rule 12(b)(1) motion challenging her claims' jurisdictional foundation—the Court sees no reason to provide leave to amend. Maher has presented her federal theory of the case, and the Court rejects it. She is now free to test her ideas on the Fifth Circuit if she wishes.

Accordingly,

IT IS ORDERED that Plaintiff Heidi Maher's Motion for Partial Summary Judgment [#17] is DISMISSED as moot;

IT IS FURTHER ORDERED that Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP's Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction [#21] is GRANTED;

IT IS FURTHER ORDERED that Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP's Rule 12(b)(6) Motion to Dismiss Non-Cognizable Claims [#42] is DISMISSED as moot;

IT IS FURTHER ORDERED that Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP's Motion for Partial Summary Judgment [#51] is DISMISSED as moot;

IT IS FURTHER ORDERED that Plaintiff Heidi Maher's Motion for Summary Judgment on Application for Declaratory Relief [#53] is DISMISSED as moot;

IT IS FURTHER ORDERED that Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP's Second Motion for Partial Summary Judgment [#71] is DISMISSED as moot;

IT IS FINALLY ORDERED that Plaintiff Heidi Maher's claims against Defendants Vaughn, Silverberg & Associates, LLP and Austin IVF, LLP are DISMISSED WITHOUT PREJUDICE for lack of subject matter jurisdiction.

SIGNED this the 5th day of March 2015.

SAM SPARKS
UNITED STATES DISTRICT JUDGE